IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ALL WAVE II TVT-O CASES**	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE TESTIMONY OF DR. MAREENI STANISLAUS

Plaintiffs respectfully request that the Court exclude, or limit in the Court's discretion, the opinions and testimony of Defendants' witness, Dr. Mareeni Stanislaus ("Dr. Stanislaus"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Stanislaus is an obstetrician/gynecologist who has not previously served as an expert witness.[1] Dr. Stanislaus seeks to offer general opinions regarding the Ethicon TVT Obturator ("TVT-O") device for the treatment of stress urinary incontinence ("SUI"). However, Dr. Stanislaus's opinions clearly exceed the bounds of her qualifications, and are founded on insufficient facts and unreliable methodology.[2] Specifically, this Court should exclude Dr. Stanislaus's opinions regarding the TVT-O device, because those opinions do not fit the facts of the case and lack a reliable methodology. Dr. Stanislaus also failed to consider literature

[1] *See* Deposition of Dr. Stanislaus, Ex. A, at 10:21-23. Dr. Stanislaus's CV is attached as Ex. B.
[2] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

contrary to her position. This Court should also exclude her opinions regarding particle loss, roping, curling, fraying, degradation, alternative materials, and the TVT-O IFU.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education."[3] The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant.[4] Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case."[5] The offered expert opinion must not go "beyond the expert[']s qualifications."[6] Further, the expert testimony must not be a mere regurgitation of factual information.[7] "A Bold statement of the experts' qualification, conclusions, and assurances of reliability are not enough to satisfy the *Daubert* standard."[8] In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant."[9]

The duty rests with Dr. Stanislaus to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly

[3] Fed. R. Evid. 702.
[4] *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).
[5] Fed. R. Evid. 702.
[6] *Hines v. Wyeth* No. 2:04-0690 2011 U.S. Dist. LEXIS 74011, at *17-18 (S.D. W. Va. July 8, 2011).
[7] *Id*. at *17.
[8] *Doe 2 v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006).
[9] *Daubert*, 509 U.S. at 597; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

admissible."[10] Even if Dr. Stanislaus is qualified and her testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."[11]

ARGUMENT

I. Dt. Stanislaus's opinions relate to midurethral slings in general, and not the TVT-O specifically, and thus do not fit the facts of the case.

Dr. Stanislaus represents that her report in this case contains her opinions regarding the TVT-O device.[12] Although Dr. Stanislaus considered scientific literature and her experience in forming her opinions, her testimony reveals that the literature and experience she relies on relate to midurethral slings in general, and not the TVT-O specifically. For example, when asked to identify the longest-term TVT-O study that she was aware of, Dr. Stanislaus could only reply: "I did not cite them appropriately. No I do not remember."[13] When asked whether she believes the TVT-O device is the "gold standard" for SUI treatment, her response was once again a generalization: "[o]nly insofar as it is part of the class of midurethral slings."[14] Dr. Stanislaus also conceded that she did not cite any TVT-O specific studies that deal specifically with laser-cut mesh.[15]

While Dr. Stanislaus also draws on her own experience, it is clear that this too is a generalization to all midurethral slings, and lacks specific detail which would inform her opinions in this case. While Dr. Stanislaus has previously implanted the TVT-O device, she admitted that "it's been about six years" since she has implanted a TVT-O.[16] When asked how many TVT-O revision procedures she has performed, she conceded "[s]pecific to the TVT-O, I

[10] *Maryland Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998).
[11] *Winebarger v. Boston Sci. Corp.* No. 2:13-cv-28892 2015 U.S. Dist. LEXIS 53892, at *6-*7(S.D. W. Va. Apr. 24, 2015).
[12] Ex. C, Expert Report of Dr. Stanislaus, at 1.
[13] Ex. A, at 114:15-21.
[14] *Id.* at 56:25-57:4.
[15] *Id.* at 94:25-95:3.
[16] *Id*. at 23:20-23.

don't remember exactly. Not very many. Perhaps two or three."[17] Moreover, Dr. Stanislaus states in her expert report that she "routinely [has] patients approach [her] at the grocery store and at social events with tears of gratitude in their eyes for the improvement they have experienced in the quality of life from the mesh sling procedure."[18] Whatever limited scientific validity such information may have is refuted by Dr. Stanislaus's testimony that she cannot recall the last time such a personal encounter would have involved a TVT-O device.[19] In short, Dr. Stanislaus's opinions in this case are merely statements about midurethral slings in general, and lack sufficient indication that these opinions have been reliably applied "to the facts of the case."[20] As such, Dr. Stanislaus's midurethral sling opinions do not fit the fact of this case and must be excluded in their entirety.

II. Dr. Stanislaus's opinions lack a reliable methodology.

Although her expert report indicates that Dr. Stanislaus considered scientific literature and her experience in forming her opinions, her deposition testimony reveals flaws in her method. For example, Dr. Stanislaus explained that she decided on what to include in her expert report by asking some of her "colleagues what generally goes in a[n] expert report."[21] She explained that her decision to discuss the IFU in her report was because "it had been a subject of question, I think, in prior litigation so I thought it might be relevant."[22] Dr. Stanislaus further conceded that she was unfamiliar with the identity of the FDA documents listed on her reliance list.[23] When asked how she determined which FDA documents to include in her report, she

[17] *Id.* at 72:20-73:3.
[18] Ex. C, at 5.
[19] Ex. A, at 40:17-41:2.
[20] Fed. R. Evid. 702; *Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *6-7.
[21] Ex. A, 50:16-24.
[22] *Id.* at 49:11-19.
[23] *Id.* at 52:6-53:9.

explained "those were provided by counsel."[24] These statements reveal that the content of Dr. Stanislaus's expert report is unreliable or otherwise outside of topics upon which she is familiar. The duty rests with Dr. Stanislaus to "come forward with evidence from which the court can determine that the proffered testimony is properly admissible."[25] Dr. Stanislaus has not done so and her opinions must be excluded as lacking sufficient indication of a reliable methodology.

III. Dr. Stanislaus's opinions about the safety of the TVT-O are unreliable because she did not consider contrary literature.

This Court has previously held that expert witnesses may not ground their opinions in merely a selective review of academic or scientific literature, choosing only materials that support their opinions, while ignoring literature that does not. Such an approach is unreliable under *Daubert* and its progeny:

> An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead selectively chooses his support from the scientific landscape. If the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.[26]

Dr. Stanislaus engages in just such selective review of scientific evidence in her attempt to support some of her opinions, while she neglects scientific scholarship refuting them. Specifically, Dr. Stanislaus engaged in a selective review of materials regarding her opinions about the safety of the TVT-O device. For example, Dr. Stanislaus's deposition testimony makes it apparent that she took no note of a 2011 peer-reviewed study by Teo, et al. which found significantly more leg pain in the TVT-O group of the study compared to the TVT-R group in

[24] *Id.* at 53:7-9.
[25] *Maryland Cas. Co.*, 137 F.3d at 783.
[26] *Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *22 (internal citations and quotations omitted); *see also Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

the study.[27] Dr. Stanislaus conceded that at the time she wrote her report in this case, she was not familiar with this study.[28] Plaintiffs acknowledge that an expert is certainly not obligated to discuss every available article regarding the product at issue. However, a diligent review of the TVT-O literature should have put this article on Dr. Stanislaus's radar. In particular, this study is (1) from a peer-reviewed journal; (2) found a statistically significant difference between the two products that Dr. Stanislaus discusses (TVT-R and TVT-O); and (3) the study was stopped due to leg pain in the TVT-O group.[29] It is clear that Dr. Stanislaus made no attempt to conduct an independent review of materials that are contrary to her opinions. Her opinions regarding the safety of the TVT-O device are unreliable because she did not account for sufficient scholarship contrary to hers and her opinions must be excluded.[30]

IV. Dr. Stanislaus's opinions about the TVT-O are unreliable because they are based on extrapolating data from other devices with different clinical outcomes.

Throughout her report, Dr. Stanislaus extrapolates data from Ethicon's Retropubic TVT device ("TVT-R") to support her opinion regarding the safety of the TVT-O device at issue in her report.[31] Dr. Stanislaus also cites to TVT-R literature to support her views of the safety of the TVT-O device.[32]

However, Dr. Stanislaus conceded at her deposition that the TVT-O and TVT-R devices have different clinical morbidities associated with each device.[33] Indeed, she admitted that the TVT-O has adverse events associated with it that are not associated with the TVT-R, such as

[27] Ex. A, 104:19-106:25.
[28] *Id*. at 107:19-24.
[29] *Id*. at 106:14-25.
[30] *See Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *22.
[31] *See* Ex. C, at 10 ("full-length polypropylene mesh midurethral slings like the TVT and TVT-O are considered the gold standard…").
[32] *Id*. at 10 at FN 36.
[33] Ex. A, at 102:3-15.

groin pain.[34] Moreover, in her report, Dr. Stanislaus states that "for women considering either a retropubic or transobturator sling" the "decision should be based on which adverse events are of greatest concern to the patient…."[35] Given these admitted clinical differences between the TVT-R and the TVT-O, Dr. Stanislaus cannot reliably extrapolate TVT-R data to attempt to support the TVT-O device.

Moreover, Dr. Stanislaus conceded that she does not intend to offer any opinions at trial about the TVT-R.[36] Since she will not be testifying regarding the TVT-R, her TVT-O opinions should be excluded to the extent that they rely on TVT-R data.

Plaintiffs fully understand that the mesh in both the TVT-O and the TVT-R is the same material; however, Dr. Stanislaus is not offering opinions about the material itself. Rather, she is offering opinions about the clinical safety of the TVT-O device, which she admits has (1) different associated clinical adverse events than the TVT-R, and (2) is a different surgical technique than the TVT-R.[37] To simply use TVT-R data to support the TVT-O is an unreliable leap and her TVT-O opinions must be excluded.

V. Dr. Stanislaus's opinion that fraying, roping, and curling do not occur with mesh in the TVT-O device, or that they have no clinical significance, is not reliable.

Dr. Stanislaus seeks to testify that she has "not seen roping, curling, of fraying of the TVT-O mesh" and that if some particle loss or fraying did occur "one would not expect that to be clinically significant."[38] But the underlying logic of Dr. Stanislaus's opinion regarding (the absence of) particle loss and mesh fraying is essentially: "I have not seen it, so it does not happen." When asked for the basis for this opinion, Dr. Stanislaus explained that:

[34] *Id.* at 101:16-21; 102:3-15.
[35] Ex. C, at 11-12.
[36] Ex. A, at 55:19-20.
[37] *Id.* 101:16-102:15; 56:6-14.
[38] Ex. C, at 16.

> Q. Doctor, is it your testimony that the mesh in the TVT-O device does not curl, rope or fray after implantation?
>
> A. Yes, that is my testimony.
>
> Q. And what is the basis for that opinion?
>
> A. Well, in the few instances that I've seen it in the body, and having made it to explant it, it was not curled, roped or frayed. It continues to be effective. And if it had roped, it would imagine it would not be so. There's also, you know, published tensile strength data on how it behaves under normal circumstances.[39]

That is simply not a reliable basis for a biomedical opinion regarding the particle loss, roping, curling, or fraying found in mesh. This Court has previously rejected this sort of "I have not seen it, therefore it must not happen" logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the "[a]bsence of evidence is not evidence of absence," and refused to allow defendant's expert to opine that certain events do not occur simply because he had not observed them in his practice.[40] By that same unassailable reasoning, Dr. Stanislaus's claim that, *in the few instances* that she has seen it in the body, it did not appear to be roped, frayed, or curled, cannot serve as a reliable scientific basis for rendering the opinions that it did not occur. Therefore, this unscientific testimony should be excluded.

VI. Dr. Stanislaus's opinions regarding the safety of meshes made of non-polypropylene material are unreliable.

Dr. Stanislaus seeks to offer various statements regarding whether "other materials such as Vypro mesh, Ultrapro mesh, or a mesh made from PVDF" would be safer than the Prolene mesh.[41] No source is cited for the statements in this paragraph, and it is unclear whether Dr. Stanislaus relied on particular studies in making these blanket statements. Thus, these statements

[39] Ex. A, at 114:25-115:11.
[40] *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014).
[41] Ex. C, at 15.

regarding the comparative safety of meshes made from "other materials such as Vypro mesh, Ultrapro mesh, or a mesh made from PVDR" must be excluded as unreliable.[42]

VII. Dr. Stanislaus's opinion that degradation does not occur with mesh in the TVT-O device, or that it has no clinical significance, is not reliable.

Dr. Stanislaus seeks to offer the opinion that literature does not show "clinically-significant degradation of Prolene mesh" and that she has not "seen any evidence of Prolene mesh degradation in [her] clinical practice."[43] Although Dr. Stanislaus considered scientific literature and her experience in forming these opinions, her deposition testimony reveals flaws in her method. In particular, her deposition testimony reveals that Dr. Stanislaus heavily relied upon her clinical experience in forming her opinions on degradation, even though her experience with such topics is lacking. For example, Dr. Stanislaus testified that she has never looked at a polypropylene mesh under a microscope."[44] Moreover, Dr. Stanislaus does not ask pathologists about degradation.[45] She explains that she has "no reason to ask a pathologist" about degradation.[46] She declines to ask pathologists about degradation because "that hasn't really been a question I would think to ask."[47] Dr. Stanislaus provides the following basis to support her degradation opinions: "I have patients now that I have been seeing since 2002, and their meshes are still in place. So [I] presume they are still there working without degradation."[48] This Court has considered and excluded expert testimony under similar circumstances.[49]

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[42] *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known.").
[43] Ex. C, at 15.
[44] Ex. A, at 78:7-10.
[45] *Id.* at 78:11-17; 78:18-79:7.
[46] *Id.* at 78:24-79:7.
[47] *Id.* at 78:11-17.
[48] *Id.* at 77:6-9.
[49] *See Winebarger*, 2015 U.S. Dist. LEXIS 53892, at *101-103 (excluding the Dr. Culligan's opinions on physical properties of polypropylene mesh).

Dr. Stanislaus also testified that she was not aware of any Ethicon employee testimony about degradation, and "she is not quite sure why that would be relevant to [her] opinion."[50] Dr. Stanislaus also testified that while she has "tested" a TVT-O for degradation—this "testing" is little more than her visual inspection of the mesh.[51] When asked how many TVT-O revision procedures she had actually performed, however, she conceded that it was "[n]ot very many. Perhaps two or three."[52] Dr. Stanislaus' opinions on degradation must be excluded because they lack a reliable basis.

VIII. Dr. Stanislaus is not qualified to offer opinions about the adequacy of the TVT-O IFU.

Dr. Stanislaus is an obstetrician/gynecologist who lacks special qualifications in law or regulatory matters. As this Court has previously held, medical experts are not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience.[53] Dr. Stanislaus offers just such opinions in her report. For example, she opines, among other things, that the TVT-O IFU "warnings, precautions, and adverse reactions section of the IFU make it clear to surgeons that temporary or chronic pain and dyspareunia could result."[54] Moreover, no source is cited for the previous statement, as well as many of the other statements in this section of the report, and there is no implication that Dr. Stanislaus relied on scientific studies in making this particular blanket statement. Thus, these statements regarding the IFU must be excluded as unreliable.[55]

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[50] Ex. A, at 91:10-25.
[51] *Id.* at 77:10-18.
[52] *Id.* at 72:25-73:3.
[53] *See Sederholm*, 2016 U.S. Dist. LEXIS 77070, at *41 (excluding urologist's expert opinions on the adequacy of the defendant's IFU that he based solely on the risks he observed in his practice).
[54] Ex. C, at 17-18. Dr. Stanislaus testified that she does not consider the TVT-O IFU to be important in her practice, but she included it in her report "because it was my understanding that Plaintiffs' experts may refer to the IFU. I thought it would be an important thing to discuss." *Id.* at 64:8-17.
[55] *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known.").

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Stanislaus is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and her testimony should be excluded.

Dated: July 28, 2016

By: /s/ Edward A. Wallace

Edward A. Wallace
Mark R. Miller
Timothy E. Jackson
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
T. (312) 346-2222
F. (312) 346-0022
E. eaw@wexlerwallace.com
mrm@wexlerwallace.com
tej@wexlerwallace.com

CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace